In re Application of:	Palmieri et al.	Docket No.:	2006P26237 US
Application No.:	10/813,604	Examiner:	WRIGHT
Filed:	3/31/2004	Art Unit:	1797
Customer No.:	26474	Confirmation No.:	4357

For: Multipath access system for use in an automated immunoassay analyzer

Honorable Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

APPEAL BRIEF UNDER 37 C.F.R. § 41.37

Sir:

This is an appeal, pursuant to 37 C.F.R. § 41.31(a), from the rejection dated April 6, 2009, reopening prosecution after the filing of an appeal brief on January 5, 2009. A Notice of Appeal is filed concurrently herewith. No additional fees are required for the filing of this brief pursuant to 35 U.S.C. § 134(a). Please charge any shortage in fees due in connection with the filing of this paper, including Extension of Time fees, to Deposit Account 14.1437. Please credit any excess fees to such account.

REAL PARTY IN INTEREST:

The real party in interest is Siemens Healthcare Diagnostics Inc., of Tarrytown, NY.

RELATED APPEALS AND INTERFERENCES:

To the best of the undersigned's knowledge, there are no related interferences or judicial proceedings.

STATUS OF CLAIMS:

- Claims 27 – 47 are pending in the application.
- Claims 27 – 47 are rejected.
- Claims 27 – 47 are the subject of this appeal.
- No claims are allowed or confirmed.
- Claims 1 – 26 are canceled.

STATUS OF AMENDMENTS:

No amendment subsequent to final rejection has been made as this brief is filed in response to the non-final rejection of April 6, 2009, which represents the third rejection of the claims of this application.

SUMMARY OF CLAIMED SUBJECT MATTER:

Independent claim 27 is directed to a multipath access system for use in an automated immunoassay analyzer[1], comprising: (a) a transport device,[2] (b) a transfer station,[3] and (c) a programmable controller.[4] The transport device comprises (i) means

[1] Specification page 2, lines 10 – 15.
[2] Specification page 3, lines 13 – 14.
[3] Specification page 3, lines17 – 19.
[4] Specification page 3, lines 19 – 23.

for holding a plurality of vessels,[5] and (ii) means for moving the vessel holding means in a continuous loop.[6] The transfer station comprises a means for moving vessels to and from the vessel holding means.[7] The programmable controller is programmed to determine an individual path along the continuous loop for each of the vessels.[8] The determination of each path is based on a resource requirement associated with each vessel.[9]

Claim 28 is directed to the multipath access system of claim 27, wherein the resource requirement associated with each vessel includes one or more tests, operations, and/or assays to be performed in each vessel.[10]

Claim 29 is directed to the multipath access system of claim 27, wherein the programmable controller is programmed to receive information regarding the resource requirement associated with each vessel, and wherein the paths determined by the controller do not depend on the order in which the controller receives the information.[11]

Claim 30 is directed to the multipath access system of claim 27, wherein the path determined for at least one vessel, requires the transfer station to move at least one vessel to or from the vessel holding means.[12]

Claim 31 is directed to the multipath access system of claim 27, further comprising a second transport device.[13] The second transport device comprises second means for holding a plurality of vessels,[14] and second means for moving the vessel

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[5] Specification page 3, lines 13 – 14; FIG. 2 illustrates Vessel Holding Member 207; and FIGs. 7 and 8, illustrating embodiments having multiple transport devices each comprising means for holding a plurality of vessels.

[6] Specification page 3, lines 13 – 16, FIG. 2 illustrates Incubator Belt 202, and FIGs. 7 and 8 illustrate embodiments having multiple transport devices each comprising means for holding a plurality of vessels, and Incubator Chains 802. At page 14, lines 4 – 14, the specification discusses various incubator belt arrangements.

[7] Specification page 5, lines 18 – 23; page 9, lines 9 – 11; 20A and 20B in FIG. 2, page 10, line 5 – page 11, line 16. FIGs. 3A, 3B, 3C, 3D, 4A, 4B, 4C, and 4D also illustrate means for moving vessels to and from the vessel holding means.

[8] Specification page 2, line 24 – page 3, line 2.

[9] Specification page 2, line 24 – page 3, line 2.

[10] Specification page 11, lines 21 – 26.

[11] Specification page 2, line 24 – page 3, line 2; and specification page 11, lines 21 – 26.

[12] Specification page 13, lines 5 – 19.

[13] Specification page 2, lines 13 – 15.

[14] Specification page 3, lines 13 – 14; FIG. 2 illustrates Vessel Holding Member 207, and FIGs. 7 and 8, illustrating embodiments having multiple transport devices each comprising means for holding a plurality of vessels.

holding means in a continuous loop.[15] Claim 31 also requires the transfer station to comprise a means for moving vessels (i) from the vessel holding means of the first transport device to the vessel holding means of the second transport device, and (ii) from the vessel holding means of the second transport device to the vessel holding means of the first transport device.[16]

Claim 32 is directed to the multipath access system of claim 27, further comprising a delivery station for delivering one or more vessels to the transport device.[17]

Claim 33 is directed to the multipath access system of claim 27, further comprising a pipetting station for adding one or more reagents to a vessel positioned in a vessel holding means.[18]

Claim 34, is directed to the multipath access system of claim 27, further comprising a wash station for washing vessels.[19]

Claim 35 is directed to the multipath access system of claim 34, wherein the wash station is combined with the transfer station.[20]

Claim 36 is directed to the multipath access system of claim 27, further comprising an agitating assembly positioned adjacent to the transport device at a location where at least one test vessel held in a vessel holding means contacts the agitating assembly.[21]

Claim 37 is directed to the multipath access system of claim 36, wherein the agitating assembly is stationary.[22]

Claim 38, is directed to the multipath access system of claim 27, wherein the means for moving the vessel holding means is adapted to move the vessels clockwise

[15] Specification page 3, lines 13 – 16, FIG. 2 illustrates Incubator Belt 202; and FIGs. 7 and 8 illustrate embodiments having multiple transport devices each comprising means for holding a plurality of vessels, and Incubator Chains 802. At page 14, lines 4 – 14, the specification discusses various incubator belt arrangements.
[16] Specification page 5, lines 18 – 23; page 4, lines 11 – 13; page 4, line 14 – page 5, line 5; page 9, lines 9 – 11; 20A and 20B in FIG. 2; page 10, line 5 – page 11, line 16. FIGs. 3A, 3B, 3C, 3D, 4A, 4B, 4C, and 4D also illustrate means for moving vessels to and from the vessel holding means.
[17] Specification page 3, line 16.
[18] Specification page 3, lines 23 – 25.
[19] Specification page 3, lines 25 – 27.
[20] Specification page 3, lines 27 – 28.
[21] Specification page 4, lines 8 – 13.
[22] Specification page 4, line 11.

and/or counterclockwise around the continuous loop.[23]

Independent Claim 39 is directed to a multipath access system for use in an automated immunoassay analyzer[24], comprising: (a) a transport device[25], comprising (i) a plurality of vessel holders each for holding a vessel[26], and (ii) a mechanism for moving the vessel holders in a continuous loop,[27] (b) a transfer station, comprising a transfer shuttle, positioned to slide in a direction perpendicular to a portion of the transporter device, for moving vessels to and from the vessel holders[28], (c) a programmable controller, programmed to determine an individual path along the continuous loop for each of the vessels[29], wherein the determination of each path is based on a resource requirement associated with each vessel[30].

Independent claim 47 is directed to a method for controllably moving samples in an automated immunoassay analyzer[31] comprising: determining an individual path along a first continuous loop for each of a plurality of samples based on a resource requirement for each sample[32], optimizing the path determined for each sample such that samples having identical resource requirements travel an equal distance around the first continuous loop, wherein for at least one sample the equal distance comprises the sum of a first distance and a second distance, wherein the first distance is traveled in a clockwise direction around the first continuous loop, wherein the second distance is traveled in a counterclockwise direction around the first continuous loop, and wherein the path

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[23] Specification page 12, lines 13 – 14.
[24] Specification page 2, lines 10 – 15.
[25] Specification page 3, lines 13 – 14.
[26] Specification page 3, lines 13 – 14; FIG. 2 illustrates Vessel Holding Member 207; and FIGs. 7 and 8, illustrating embodiments having multiple transport devices each comprising means for holding a plurality of vessels.
[27] Specification page 3, lines 13 – 16, FIG. 2 illustrates Incubator Belt 202, and FIGs. 7 and 8 illustrate embodiments having multiple transport devices each comprising means for holding a plurality of vessels, and Incubator Chains 802. At page 14, lines 4 – 14, the specification discusses various incubator belt arrangements.
[28] Specification page 5, lines 18 – 23; page 9, lines 9 – 11; 20A and 20B in FIG. 2, page 10, line 5 – page 11, line 16. FIGs. 3A, 3B, 3C, 3D, 4A, 4B, 4C, and 4D also illustrate means for moving vessels to and from the vessel holding means.
[29] Specification page 3, lines 19 – 23.
[30] Specification page 2, line 24 – page 3, line 2.
[31] Specification page 2, lines 10 – 15.
[32] Specification page 3, lines 13 – 16, FIG. 2 illustrates Incubator Belt 202; and FIGs. 7 and 8 illustrate embodiments having multiple transport devices each comprising means for holding a plurality of vessels, and Incubator Chains 802. At page 14, lines 4 – 14, the specification discusses various incubator belt arrangements.

determined for at least one sample includes transferring the sample from the first continuous loop to a second continuous loop.[33]

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL:

Whether the Office action erred in rejecting:

I. claims 42 – 44 under 35 U.S.C §112, second paragraph;

II. claims 27 – 34, 38, 39, 41 and 45 – 47 as being anticipated by Carey et al., U.S. Patent No. 5,827,478 ("Carey");

III. claims 35 – 37 and 40 under 35 U.S.C §103(a) over Carey in view of U.S. Pat. No. 5,885,529 to Babson et al. (hereinafter, "Babson").

ARGUMENT:

Regarding Rejection I:

Appellants respectfully submit that the rejection of claims 42 – 44 under 35 U.S.C §112, second paragraph is in error.

Claims 42 – 44 are dependent claims, which depend from and further limit independent claim 39. Contrary to the position of the Office action, claims 42 – 44 are not incomplete and do not omit any essential matter, i.e., matter disclosed to be essential to the invention as described in the specification. See MPEP 2172.01. Dependent claims 42 – 44 manifestly cannot be "incomplete" if the independent claim from which they depend, here claim 39, is complete, as claims 42 – 44 merely add limitations to claim 39.

Here, claim 39 sets forth a transfer station, comprising a transfer shuttle,

[33] Specification page 12, line 1 – page 13, line29.

positioned to slide in a direction perpendicular to a portion of a transporter device, for moving vessels to and from the vessel holders. Claim 42 specifies that the transfer shuttle is positioned so that upon sliding in a direction perpendicular to a portion of the transporter device, a first projecting member contacts a first test vessel held in a vessel holding means and pushes the first test vessel from the transport device into the transfer station, while a second projecting member contacts a second test vessel held in the transfer station and pushes the second test vessel out of the transfer station.

The Office action alleges that it is not clear from the claim "how upon sliding the transfer shuttle, a first projecting member contacts a first test vessel, and a second projecting member contacts a second test vessel. How are these elements structurally connected?" To the contrary, it is not the function of the claims to explain how an invention works; that is the province of the written description in the specification. *S3 Inc. v. nVIDIA Corp.*, 259 F.3d 1364, 59 USPQ2d 1745 (Fed. Cir. 2001). The test for definiteness is simply whether one skilled in the art would understand the bounds of the claim when read in light of the specification. *Exxon Research & Engineering Co. v. United States,* 265 F.3d 1371, 60 USPQ2d 1272 (Fed. Cir. 2001).

Here, the specification clearly explains how upon sliding the transfer shuttle, a first projecting member contacts a first vessel, and a second projecting member contacts a second vessel. See p. 10, line 28 – page 11, line 16. The scope of claim 42 is readily understood by anyone of skill in the art and is not indefinite as alleged. This ground of rejection should be reversed.

Regarding Rejection II:

Appellants respectfully submit that the rejection of claims 27 – 34, 38, 39, 41 and 45 – 47 as being anticipated by Carey is in error and should be reversed.

Carey discloses in Fig. 1 an immunoassay analyzer instrument having a cuvette hopper feeder 20 that feeds empty cuvettes into a preheat chamber 22, which leads to a cuvette entrance chute of an incubation chamber 12. The empty cuvettes are fed through the entrance chute and disposed into slots (i.e., 1 – 115) of cuvette ring 32 of the chamber. The ring 32 holds the cuvettes as they move around the chamber. In operation, the plurality of probe stations 24 are disposed around the circumference of the chamber

12 at predetermined locations and are arranged to either aspirate or dispense fluids to or from the cuvettes at fixed positions around the chamber 12. Col. 6, lines 27 – 64.

Contrary to the invention of claim 27, Carey fails to disclose a programmable controller, programmed to determine an individual path along the continuous loop for each of the vessels, wherein the determination of each path is based on a resource requirement associated with each vessel. The control system 25 determines only a particular order in which to process assays, such as first-in-first-out (FIFO), to maximize throughput. Col. 4, lines 9 – 15.

The Carey device functions in a completely different manner than that disclosed and claimed in the present application. According to Carey, different assay protocols are implemented by adding reagent to particular cuvettes in the incubation chambers at different times. See col. 4, line 67 – col. 5, line 21. This is achieved by providing multiple reagent probes (e.g., probes 24i – 24m, Fig. 1) at fixed, predetermined locations in the incubation chamber to achieve desired timing. See col. 6, lines 27 – 36.

Contrary to the Carey apparatus, the claimed invention provides a programmable controller to determine an individual path for each of the test vessels in the transport device, based on a resource requirement associated with each vessel. See specification at p. 12, lines 1 – 25. In particular, the invention provides that each test vessel is moved along the continuous loop according to the assay requirements of the particular test vessel. This is not done in Carey. As disclosed with respect to Fig. 8, the Carey apparatus operates on a fixed "cuvette cycle" in which all cuvettes are moved according to a predetermined path. See col. 19, line 45 – col. 20, line 58. As explained at col. 22, lines 21 – 56, different test protocols are implemented by dispensing reagent into specific cuvettes at specific locations along the incubation chamber, to thereby control the timing of incubation. There is no calculation of any individual path along a continuous loop as claimed. Each of independent claims 27, 39 and 47 set forth this feature.

Further, Carey fails to disclose the claimed transfer station comprising means for moving vessels to and from vessel holding means of the transport device. According to Carey, the cuvettes simply fall out of a chute into one of the slots in the cuvette ring 32. Col. 5, lines 58 – 61. An elevator mechanism as shown in Fig. 7 includes a lift rod 192 that pushes a cuvette 84 out of the incubation chamber and into a luminometer 14. Col.

18, line 56 – col. 19, line 9. Thus, the elevator mechanism 190 does not correspond to the claimed transfer station that moves vessels to <u>and</u> from vessel holding means of the transport device.

<u>Regarding Rejection III</u>:

Appellants respectfully submit that the rejection of claims 35 – 37 and 40 under 35 U.S.C §103(a) over Carey in view of Babson is in error and should be reversed.

Claim 35 is dependent ultimately from independent claim 27, and further requires that the wash station be combined with the transfer station. The Office action's allegation that this configuration would have been an obvious modification of Carey in view of the disclosure of Babson, is erroneous. In particular, there is not any "transfer station in the wash station 214" of Babson as alleged. The side track chain 213b (Figs. 2A-2B) does not constitute any part of the wash station 214 as alleged. In any event, there is provided no basis for the apparent suggestion to combine a wash station with the elevator mechanism 190 of Carey, and in fact such combination would make no sense. As explained above, the elevator mechanism functions to push a cuvette 84 into the luminometer 14 from the incubation chamber 12. Carey already provides wash stations 24f, h and i at fixed positions along the incubation chamber, which are selected to correlate with the assay protocols being performed. <u>See</u> col. 6, lines 27 -31. To remove the wash stations from their selected positions thus would prevent the protocols from being performed as desired. Further, the elevator mechanism 190 is <u>not</u> a transfer station as claimed but is simply a one-way push-rod mechanism. Thus, locating a wash station proximate this push-rod mechanism would not result in a combined wash station and transfer station as claimed.

Similarly, claims 36 and 37 require an agitating assembly positioned adjacent to the transport device at a location where at least one test vessel contacts the agitating assembly. The Office action has failed to establish even a *prima facie* case of obviousness with respect to claim 36. The Office action refers to disclosure of reaction tube shaker bars, not even shown in Babson, and from this concludes that such shaker bars would have been obviously positioned "adjacent the transport device" "when the transport device is moved in the system of Carey." However, the incubation chamber 12

of Carey is a closed chamber, as shown in Fig. 2. Shaker bars thus could not be positioned adjacent to the incubation chamber and have any effect on the cuvettes positioned in the slots within the incubation chamber 12. This ground of rejection is in error.

Similarly, the rejection of dependent claim 40 is in error. This claim sets forth that the transfer shuttle comprises a horizontal support and at least two projecting members projecting from the horizontal support, wherein the projecting members are spaced far enough apart to accommodate a test vessel therebetween. See Figs. 3A- 3B, members 32A, 32B. The Office action proposes to include two projecting members in the "horizontal support" of Carey's "transfer shuttle," purportedly as taught by Babson. This ground of rejection is untenable. First, Carey does not even disclose a transfer shuttle as claimed. The elevator mechanism 190 (Fig. 7) does not correspond to the claimed transfer shuttle. There is no horizontal support member in such elevator mechanism upon which to mount any projecting members. Second, in Carey the lift rod 192 pushes the cuvette 84 into the luminometer 14 through a narrow entrance shaft 196. Consequently, "increasing the lateral stability" of the cuvette is a concept that does not apply to the Carey structure, as the cuvette is constrained by the diameter of the entrance shaft 196. The proposed modification of Carey would not have been made by one having any skill in the art, and this ground of rejection is thus in error and must be reversed.

In Conclusion:

Appellants respectfully submit the present application to be in condition for allowance, and request that all grounds of rejection be reversed.

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CLAIMS APPENDIX:

27. A multipath access system for use in an automated immunoassay analyzer, comprising:
    (a) a transport device, comprising
        (i) means for holding a plurality of vessels, and
        (ii) means for moving the vessel holding means in a continuous loop,
    (b) a transfer station, comprising a means for moving vessels to and from the vessel holding means,
    (c) a programmable controller, programmed to determine an individual path along the continuous loop for each of the vessels,
    wherein the determination of each path is based on a resource requirement associated with each vessel.

28. The multipath access system of claim 27, wherein the resource requirement associated with each vessel includes one or more tests, operations, and/or assays to be performed in each vessel.

29. The multipath access system of claim 27, wherein the programmable controller is programmed to receive information regarding the resource requirement associated with each vessel, and wherein the paths determined by the controller do not depend on the order in which the controller receives the information.

30. The multipath access system of claim 27, wherein the path determined for at least one vessel, requires the transfer station to move at least one vessel to or from the vessel holding means.

31. The multipath access system of claim 27, further comprising a second transport device comprising second means for holding a plurality of vessels, and second means for moving the vessel holding means in a continuous loop, and

wherein the transfer station comprises a means for moving vessels

(i) from the vessel holding means of the first transport device to the vessel holding means of the second transport device, and

(ii) from the vessel holding means of the second transport device to the vessel holding means of the first transport device.

32. The multipath access system of claim 27, further comprising a delivery station for delivering one or more vessels to the transport device.

33. The multipath access system of claim 27, further comprising a pipetting station for adding one or more reagents to a vessel positioned in a vessel holding means.

34. The multipath access system of claim 27, further comprising a wash station for washing vessels.

35. The multipath access system of claim 34, wherein the wash station is combined with the transfer station.

36. The multipath access system of claim 27, further comprising an agitating assembly positioned adjacent to the transport device at a location where at least one test vessel held in a vessel holding means contacts the agitating assembly.

37. The multipath access system of claim 36, wherein the agitating assembly is stationary.

38. The multipath access system of claim 27, wherein the means for moving the vessel holding means is adapted to move the vessels clockwise and/or counterclockwise around the continuous loop.

39. A multipath access system for use in an automated immunoassay analyzer, comprising:

(a) a transport device, comprising

(i) a plurality of vessel holders each for holding a vessel, and

(ii) a mechanism for moving the vessel holders in a continuous loop,

(b) a transfer station, comprising a transfer shuttle, positioned to slide in a direction perpendicular to a portion of the transporter device, for moving vessels to and from the vessel holders,

(c) a programmable controller, programmed to determine an individual path along the continuous loop for each of the vessels,

wherein the determination of each path is based on a resource requirement associated with each vessel.

40. The multipath access system of claim 39, wherein the transfer shuttle comprises a horizontal support and at least two projecting members, wherein the projecting members project from the horizontal support, and wherein the projecting members are spaced far enough apart to accommodate at least one test vessel therebetween.

41. The multipath access system of claim 39, wherein the transfer shuttle is positioned so that upon sliding in a direction perpendicular to a portion of the transporter device, a projecting member contacts a test vessel held in a vessel holding means and pushes the test vessel from the transport device.

42. The multipath access system of claim 39, wherein the transfer shuttle is positioned so that upon sliding in a direction perpendicular to a portion of the transporter device, a first projecting member contacts a first test vessel held in a vessel holding means and pushes the first test vessel from the transport device into the transfer station, while a second projecting member contacts a second test vessel held in the transfer station and pushes the second test vessel out of the transfer station.

43. The multipath access system of claim 42, wherein the second projecting member

contacts the second test vessel held in the transfer station and pushes the second test vessel out of the transfer station into a wash station, into a luminometer subsystem, or into a vessel holding means of a second transport device.

44. The multipath access system of claim 42, wherein the transfer station is combined with a wash station.

45. The multipath access system of claim 27, wherein the path determined for each vessel is optimized such that vessels having identical resource requirements travel an equal distance around the continuous loop.

46. The multipath access system of claim 45, wherein for at least one vessel the equal distance comprises the sum of a first distance and a second distance,
wherein the first distance is traveled in a clockwise direction around the continuous loop, and
wherein the second distance is traveled in a counterclockwise direction around the continuous loop.

47. A method for controllably moving samples in an automated immunoassay analyzer comprising:
determining an individual path along a first continuous loop for each of a plurality of samples based on a resource requirement for each sample,
optimizing the path determined for each sample such that samples having identical resource requirements travel an equal distance around the first continuous loop,
wherein for at least one sample the equal distance comprises the sum of a first distance and a second distance,
wherein the first distance is traveled in a clockwise direction around the first continuous loop,
wherein the second distance is traveled in a counterclockwise direction around the first continuous loop, and

wherein the path determined for at least one sample includes transferring the sample from the first continuous loop to a second continuous loop.

EVIDENCE APPENDIX:

None.

RELATED PROCEEDINGS APPENDIX:

None.